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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,676	09/27/2001	Yem Chin	BSX-219	8991

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Washington, DC 20004-2615

EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,676

Applicant(s)

CHIN ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-14,16-18,20-23,25-29,31,32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,21-23,25,26 and 34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-29,31 and 32 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9,12-14,16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

There are three types of surgical knives disclosed

- | | | |
|------|--|--------------------------------------|
| I. | A knife with detents and radiopaque indicia. | Claims 1-3, 5-7, 9, 12-14, 16-18, 20 |
| II. | A cable actuated needle knife. | Claims 10-11 |
| III. | A knife with visual indicia. | Claims 21-26 |

Additionally two distinct methods are claims

- | | | |
|----|---|---------------------|
| A. | Method of using tool of group I. | Claims 27-29, 31-32 |
| B. | Method of restraining a surgical blade. | Claim 34 |

Applicant should elect one invention from each group above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none appear generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Steven War on Nov 11, 2003 a provisional election was made without traverse to prosecute the invention of Species I and A, claims 1-3, 5-7, 9, 12-14, 16-18, 20, 27-29, and 31-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-11, 21-23, 25-26, and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 9, 12-14, 16-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Heeron et al. (O'Heeron) US 5609604 in view Ganz et al. US 5810807. O'Heeron discloses a trocar (or catheter) having a distally located cutting device (figure 2) in a lumen thereof (80, figure 6) comprising an exposed linear cutting member (15). Said device contains spaced detents (28b) to interact with one or more notches (near 38b) in the distal end of said lumen to provide movement resistance. Spaced detents (48) are provided on the cutting device (figure 5) which interact with notches on the distal end of the lumen. O'Heeron is silent with respect to the step of improving his tool by adding radiopaque rings or bands to the device to provide the device with the capability of being imaged to enable a surgeon to determine the location of the blade in vivo. The applicant asserts the step of adding radiopacity to a surgical blade is novel to the art. However US patents 5241970, 5292305, 5810807, 5549625, and 5226909 all disclose the well-known technique of making an endoscope blade radiopaque to render the blade visible under fluoroscopy. Ganz et al. '807 teaches, "As also shown in FIGS. 1 and 2, the distal tip 16 of the distal end segment 28 is preferably tapered to the end opening 33 and maybe formed of a radiopaque material. The junction 26 may be marked by a wide band of radiopaque material. A plurality of distance markers 74 may be formed along the distal end

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segment 28 for the physician to use in judging how far to withdraw the distal end segment 28 prior to retracting the cutting wire 40 and making the incision.” At the time of the invention it would have been obvious to one having ordinary skill in the art to add the Ganz ‘807 radiopaque bands to the cutting member to allow the device to be measured under fluoroscopy. The cutting member is considered a “needle knife”. Indicia are capable of being referenced from the middle and alternatively referenced along the length of the cutting member. The indicia inherently can be used to determine the length of the deployed cutting member.

Allowable Subject Matter

Claims 27, 28, 29, 31, and 32 are allowed.

The following is an examiner’s statement of reasons for allowance: The method claims substantially repeat the language of the apparatus claims, but there is a substantial difference. The method step of using the radiopaque indicia to measure the length of the blade is not stated by O’Heeron. While the combined O’Heeron device is inherently capable of being measured this way, it would not have been obvious to do so in view of the references cited by the examiner. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Response to Arguments

Applicant's arguments with respect to claims 1-3,5-7,9-14,16-18,20-23,25-29,31,32 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

Multiple claims in the applicant's application are substantial duplicates of each other. For example claim 2 is the same as claim 12. Claim 12, for example, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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12/01/03


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